

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
MARTINSBURG**

UNITED STATES OF AMERICA,

Plaintiff,

v.

**CIVIL ACTION NO. 3:16-CV-24
(BAILEY)**

**CITY PHARMACY, LLC,
CITY PHARMACY OF CHARLES TOWN, INC.,
DAVID M. WASANYI, AMY WASANYI, and
ROGER LEWIS,**

Defendants.

**ORDER ON DEFENDANT DAVID M. WASANYI'S MOTION TO DISMISS
AND MOTION TO STRIKE EXPERT TESTIMONY AND GRANTING IN PART AND
DENYING IN PART GOVERNMENT'S MOTION FOR SUMMARY JUDGMENT**

This matter now comes before the Court for consideration of defendant David M. Wasanyi's ("Wasanyi") Motion to Dismiss [Doc. 58], filed on September 22, 2016. The Government filed a Response in Opposition to Wasanyi's Motion to Dismiss on September 29, 2016 [Doc. 60]. The Government then filed a Motion for Summary Judgment [Doc. 68] on December 29, 2016. As to defendant Amy Wasanyi (now "Amy Louise"¹ and hereinafter referred to as "Amy Louise" or "Louise"), this Court entered an Agreed Order Extending Time for Defendant Amy Wasanyi to File a Response to Plaintiff's Motion for Summary Judgment [Doc. 81] on January 19, 2017. Amy Louise then filed her Response in Opposition [Doc. 85] on February 2, 2017, to which the Government filed a Reply [Doc.

¹ This Court notes that at the time that this action was filed, Amy Louise was still married to David Wasanyi [Doc. 85 at 1]. However, on July 13, 2016, the Family Court of Berkeley County entered a Final Order granting her petition for divorce from David Wasanyi, after which time she legally changed her name to Amy Louise [Id.].

88] on February 7, 2017. Defendant Roger Lewis (“Lewis”) filed a Response in Opposition to the Motion for Summary Judgment [Doc. 94] on February 17, 2017, to which the Government filed a Reply [Doc. 95] on February 22, 2017. Finally, defendant Wasanyi then filed a Motion to Strike Expert Testimony [Doc. 96] on February 28, 2017, to which the Government filed a Response [Doc. 98] on March 10, 2017. For the following reasons, defendant Wasanyi’s Motion to Dismiss and Motion to Strike are **DENIED**. The Government’s Motion for Summary Judgment is **GRANTED** as to defendant David M. Wasanyi, and **DENIED AS MOOT** as to defendants Roger Lewis and Amy Louise.² Finally, defendant Wasanyi’s Motion for Extension of Time to File Voir Dire, Jury Instructions, and Verdict Form is **GRANTED**.

I. Background

On February 29, 2016, the Government filed a complaint against the above-named defendants, alleging violations of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §§ 801-971 (“the CSA”), and seeking civil penalties for the same [Doc. 1]. Specifically, the United States alleges violations of 21 U.S.C. § 842(a)(1), 21 U.S.C. § 829, 21 C.F.R. § 1306.04, 21 C.F.R. § 1306.05 and 21 C.F.R. § 1306.11 [Id.].

² This Court notes that during an April 4, 2017, Telephonic Status Conference between the parties and this Court, the Government and defendants Lewis and Louise had reached a settlement as to the claims against those defendants. In a follow up conversation with chambers staff, the Government further represented that it had reached a settlement agreement with CP and CPCT as well, given that defendant Louise has now assumed responsibility for those organizations. On April 12, 2017, those parties filed a Proposed Consent Judgment [Doc. 114] with this Court, which this Court signed on April 18, 2017 [Doc. 115]. Accordingly, this Court need not consider the portions of the Government’s Motion for Summary Judgment as to defendants Lewis, Louise, CP, and CPCT, as those claims are moot.

The Government claims that the individual defendants utilized City Pharmacy, LLC (“CP”), and City Pharmacy of Charles Town, Inc. (“CPCT”), to fill illegitimate prescriptions for controlled substances, including those which were: (1) written by medical providers located in distant states; (2) presented by individuals who traveled from distant locations; (3) paid for using cash; (4) altered by scratching out the medical provider’s fill date, increasing the number of units being prescribed or changing the strength, nature or type of controlled substance; and (5) lacking the full name or address of the patient for whom the prescription was written [Id.].

Defendant CP is a West Virginia limited liability company, with its principal place of business located in Martinsburg, West Virginia [Doc. 1 at ¶ 2]. Defendant CPCT is a West Virginia corporation, with its principal place of business in Charles Town, West Virginia [Id. at ¶ 3]. CP and CPCT were both registered by the U.S. Drug Enforcement Administration (“DEA”), and both companies were engaged in the business of operating a retail pharmacy [Id. at ¶¶ 4-7]. During the time of the events alleged in the Complaint, Amy and David Wasanyi were married although, again, the former Amy Wasanyi has since divorced David Wasanyi and changed her name to Amy Louise [Doc. 85 at 1]. Roger Lewis is the father of Amy Louise and former father-in-law of Wasanyi [Doc. 1 at ¶ 16]. Finally, Wasanyi was a pharmacist, licensed by the West Virginia Board of Pharmacy, and was the primary pharmacist at both CP and CPCT [Id. at ¶¶ 9-11].

In this action, the Government alleges that from 2010 into 2015, CP and CPCT filled 1,181 invalid prescriptions for Schedule II and Schedule III controlled substances, written by 45 physicians located in Florida, Georgia, Tennessee and Virginia for patients

in Alabama, Florida, Georgia, Kentucky, Maryland, Ohio, Tennessee and Virginia [Doc. 71-1³ at ¶ 8]. Most of the prescriptions (957) were written for allegedly fraudulent patients who were residents of Kentucky and Ohio [Id. at ¶ 9]. Additionally, the Government alleges that all of the purportedly fraudulent patients traveled great distances to have the prescriptions filled at CP or CPCT [Id. at ¶ 10]. In support of these allegations, the Government attached copies of the prescriptions at issue and a spreadsheet summarizing the prescriptions which, in turn, purportedly demonstrate that the vast majority of the prescriptions were written by a provider who was not located in the same state as the patient [Id. at pages 4-13].

As to defendant Wasanyi, the Government alleges that in his capacity as a pharmacist, Wasanyi filled the majority of the aforementioned 1,181 illegitimate prescriptions until his arrest in April of 2014 [Doc. 71-1 at ¶ 11]. At that time, Wasanyi was arrested and indicted by the State of West Virginia for improper delivery of controlled substances, and ultimately he faced charges in two separate Berkeley County cases and one Jefferson County case [Id. at ¶ 12]. In April of 2016, Wasanyi was convicted in the Circuit Court of Berkeley County (Case No. 15-F-17) of two counts of improper delivery of diazepam and one count of improper delivery of buprenorphine [Id. at ¶ 13]. Then, in October of 2016, Wasanyi was convicted in the Circuit Court of Berkeley County (Case No. 16-F-54) on 13 counts of improper delivery of a controlled substance [Id. at ¶ 14]. The charges in Case No. 16-F-54 involved 13 prescriptions presented by two women from

³ This Court notes that this document is a sealed Declaration of Lindsey M. Malocu, Diversion Investigator of the Drug Enforcement Administration (“DEA”) and pertains to the allegations in the Complaint.

Kentucky and written by a Georgia provider and are, in turn, allegedly similar to the 1,181 prescriptions at issue in this Federal civil action [*Id.*]. Finally, in February of 2016, Wasanyi was indicted in Jefferson County Circuit Court (Case No. 16-F-123) for his alleged role in a conspiracy to obtain controlled substances by fraud; these charges are pending [*Id.* at ¶ 15]. This action followed those related state-court matters.

II. Standard of Review

Fed. R. Civ. P. 56 provides that summary judgment is appropriate “if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.” The party seeking summary judgment bears the initial burden of showing the absence of any genuine issues of material fact. See ***Celotex Corp. v. Catrett***, 477 U.S. 317, 322-23 (1986). “The burden then shifts to the nonmoving party to come forward with facts sufficient to create a triable issue of fact.” ***Temkin v. Frederick County Comm’rs***, 945 F.2d 716, 718 (4th Cir. 1991), *cert. denied*, 502 U.S. 1095 (1992) (citing ***Anderson v. Liberty Lobby, Inc.***, 477 U.S. 242, 247-48 (1986)).

However, as the United States Supreme Court noted in ***Anderson***, “Rule 56(e) itself provides that a party opposing a properly supported motion for summary judgment may not rest upon the mere allegations or denials of his pleading, but must set forth specific facts showing that there is a genuine issue for trial.” *Id.* at 256. “The inquiry performed is the threshold inquiry of determining whether there is the need for a trial—whether, in other words, there are any genuine factual issues that properly can be resolved only by a finder

of fact because they may reasonably be resolved in favor of either party.” *Id.* at 250; see also ***Charbonnages de France v. Smith***, 597 F.2d 406, 414 (4th Cir. 1979) (Summary judgment “should be granted only in those cases where it is perfectly clear that no issue of fact is involved and inquiry into the facts is not desirable to clarify the application of the law.”) (citing ***Stevens v. Howard D. Johnson Co.***, 181 F.2d 390, 394 (4th Cir. 1950)). In reviewing the supported underlying facts, all inferences must be viewed in the light most favorable to the party opposing the motion. See ***Matsushita Elec. Indus. Co. v. Zenith Radio Corp.***, 475 U.S. 574, 587 (1986). Additionally, the party opposing summary judgment “must do more than simply show that there is some metaphysical doubt as to the material facts.” *Id.* at 586. That is, once the movant has met its burden to show absence of material fact, the party opposing summary judgment must then come forward with affidavits or other evidence demonstrating there is indeed a genuine issue for trial. Fed. R. Civ. P. 56(c); ***Celotex Corp.***, 477 U.S. at 323-25; ***Anderson***, 477 U.S. at 248. “If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted.” ***Anderson***, 477 U.S. at 249 (citations omitted).

III. Discussion

In assessing the instant Motion for Summary Judgment, this Court is satisfied that the questions before it are not factual, but rather legal, in nature. As such, this Court will decide whether the Government has asserted and proven a cognizable claim for a civil penalty as to defendant Wasanyi. See ***United States v. Butterbaugh***, 2015 WL 4660096

at *2 (W.D. Wash. Aug. 5, 2015). This Court will also rule on defendant Wasanyi's other pending motions.

A. Defendant David Wasanyi is liable for violations of 21 U.S.C. § 842(a)(1).

In deciding the disposition of Wasanyi's Motion to Dismiss [Doc. 58] and the Government's Motion for Summary Judgment [Doc. 68] as to Wasanyi, this Court is cognizant of the applicable federal regulations that applied to Wasanyi's conduct as a pharmacist during the time that he worked in that capacity at CP and CPCT. 21 U.S.C. § 842(a)(1) makes it unlawful for any person to "distribute or dispense a controlled substance in violation of [21 U.S.C. §] 829." In turn, 21 U.S.C. § 829 sets forth the rules and regulations regarding the issuance and filling of prescription drugs, while the related Code of Federal Regulations provisions, 21 C.F.R. §§ 1306.01 – 1306.27, provide the scope of 21 U.S.C. § 829.

The CSA and applicable regulations place the responsibility for the proper dispensing of controlled substances on the pharmacist that fills the prescription. See 21 C.F.R. §§ 1306.04 – 1306.06; see also **United States v. Leal**, 75 F.3d 219, 227 (6th Cir. 1996), *abrogated on other grounds by United States v. Kennedy*, 107 Fed. Appx. 518 (6th Cir. 2004) (holding that 21 U.S.C. § 841 and 21 C.F.R. § 1306.04 of the CSA scheme impose a "federal duty on [a pharmacist] to be vigilant in filling prescriptions, so as to avoid filling those that were issued for a non-medical purpose . . ."). Indeed, courts around the country have consistently held that pharmacists may be held liable for violations of 21 U.S.C. § 842. See **United States v. Poulin**, 926 F.Supp. 246, 252-253 (D. Ma. 1996); **United States v. Wilson**, 2002 WL 1397171 (W.D. Tenn. Jan. 18, 2002); **United States**

v. Barabcoff, 416 F.Supp. 606, 610 (D.D.C. 1976); *United States v. Williams*, 416 F.Supp. 611, 614 (D.D.C. 1976).

21 C.F.R. § 1306.04 provides that in order for a prescription for a controlled substance to be effective it must be issued for a legitimate medical purpose by a practitioner acting in the usual course of his professional practice. The regulation also provides that, while “[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner . . . a corresponding responsibility rests with the pharmacist who fills the prescription.” 21 C.F.R. § 1306.04; *see also* 21 C.F.R. § 1306.06. Furthermore, an order that is not issued in the usual course of professional treatment is not a prescription, and the person knowingly filling such an order is subject to the penalties specified for violations of the CSA. *Id.* As discussed by the Government’s expert witness Dr. Carmen Catizone, the Executive Director of the National Association of Boards of Pharmacy, in her Affidavit [Doc. 73-2], and the Drug Enforcement Administration (“DEA”) in its “Pharmacist’s Manual” outlining the CSA, a pharmacist has certain duties when faced with suspicious orders:

“A pharmacist is required to exercise sound professional judgment when making a determination about the legitimacy of a controlled substance prescription. Such a determination is made before the prescription is dispensed. The law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious origin. To the contrary, the pharmacist who deliberately ignores a questionable prescription when there is reason to believe it was not issued for a legitimate medical purpose may be prosecuted along with the issuing practitioner, for knowingly and intentionally distributing controlled substances. Such action is a felony offense, which may result in the loss of one’s business or professional license.”

Drug Enforcement Administration, Pharmacists Manual: An Informational Outline of the Controlled Substances Act, 2010 Ed., at p. 30. See also [Doc. 73-1 at 2].

As defined by Dr. Catizone, “a ‘red flag’ is a circumstance arising during the presentation of a prescription which creates a reasonable suspicion that the prescription is not, on its face, legitimate. The existence of a ‘red flag’ in relation to a prescription imposes on a pharmacist the obligation to conduct further and sufficient inquiry to determine whether the prescription is or is not legitimate.” [Doc. 71-2 at 4]. See **JM Pharmacy Group, Inc.**, 80 Fed.Reg. 28667-01 (2015); see also **Holiday CVS**, 77 Fed.Reg. 62316-01 (2012). In the **Holiday CVS** administrative action, the DEA concluded that “red flags” were evident where patients traveled from Kentucky and Tennessee to South Florida to obtain prescriptions for Schedule II narcotics, and then traveled to a pharmacy that was approximately 200 miles away from the physicians’ offices, to fill them. **Holiday CVS**, at 62316 - 62346. Such “red flags” are so obvious that only those who are deliberately ignorant would fill the prescription. **Id.** Accordingly, a pharmacy that ignores a red flag and fills an illegitimate prescription violates 21 C.F.R. §1306.04 and 21 U.S.C. §842(a)(1).

In this matter, Dr. Catizone avers that obvious red flags were ignored repeatedly at CP and CPCT [Doc. 73-2 at 3-5]. For example, defendant Wasanyi, by and through CP and CPCT, repeatedly filled, “pattern prescriptions,” or the same types of drugs in the same quantities from the same prescriber [Id. at 4]. The evidence also shows that Wasanyi, through CP and CPCT, filled prescriptions despite significant geographic abnormalities between the prescribing doctors and patients [Id. at 3-6]. Prescriptions were issued by

doctors in far-flung states, including Florida, Georgia, Virginia, and Tennessee, to patients in states including Alabama, Florida, Georgia, Kentucky, Maryland, Ohio, Pennsylvania, Tennessee, and Virginia [Id.]. Dr. Catizone also represents that CP and CPCT filled nearly 1,181 illegitimate prescriptions written by 45 separate physicians located in Florida, Georgia, Tennessee, and Virginia [Doc. 73-1 at 2; 4-5].

The Government also offers the testimony of DEA Diversion Investigator Lindsey Malocu, who represents that, until he was indicted and arrested by the State of West Virginia in April of 2014, Wasanyi filled nearly all of the illegitimate prescriptions presented and filled at CP and CPCT [Doc. 71-1]. Furthermore, Amy Louise testified that Wasanyi was an organizer, owner and manager of CP and CPCT [Doc. 71-3 at 21-22]. Indeed, Wasanyi chose the pharmaceutical companies from which CP and CPCT would order narcotics, and would instruct her to call those companies to fulfill orders [Id. at 26-27]. Indeed, until he was arrested and charged with felonies in Berkeley County in April of 2014, David Wasanyi was the principal pharmacist at CP, where most of the illegitimate prescriptions were presented and filled [Doc. 71-1]. Accordingly, this Court finds that there is no genuine issue of material fact that Wasanyi was involved in the manufacture, distribution and dispensing of controlled substances within the meaning of 21 U.S.C. § 822, and is subject to the prohibitions in 21 U.S.C. § 842(a)(1). Because Wasanyi, as a licensed pharmacist in charge of CP and CPCT, repeatedly filled prescriptions for controlled substances that were not valid, Wasanyi is liable for violations of § 842(a)(1). See 21 C.F.R. § 1306.04; **Poulin**, 926 F.Supp. at 252-253; **Wilson**, 2002 WL 1397171; **Barabcoff**, 416 F.Supp. at 610; **Williams**, 416 F.Supp. at 614. Accordingly, Wasanyi's

Motion to Dismiss is denied and the Government's Motion for Summary Judgement as to Wasanyi is granted.

B. This Court Will Conduct an Evidentiary Hearing on Damages to be Assessed Against David Wasanyi.

In cases, such as this instant matter, a defendant who has been found liable for violating 21 U.S.C. § 842(a)(1), "shall be subject to a civil penalty of not more than \$25,000," for any such violation. 21 U.S.C. § 842(c)(1)(A). As noted above, the evidence in this case supports a grant of summary judgment against defendant Wasanyi for violations of § 842(a)(1). Accordingly, at a date and time to be determined by this Court, the parties must be prepared to present evidence and argument on the issue of the penalty amount. This Court will conduct a Bench Trial and determine such the penalty amount to be assessed against defendant Wasanyi at that time.

C. Defendant Wasanyi's Motion to Strike and Motion for Hearing on the Motion to Strike Must be Denied. However, Defendant Wasanyi's Motion for Extension of Time is Granted.

On February 28, 2017, Wasanyi filed a Motion to Strike Dr. Catizone's Affidavit [Doc. 96], wherein he argues that Dr. Catizone's expert opinions set forth in an Affidavit [Doc. 69-2] should be struck. He argues that Dr. Catizone's testimony somehow violates the Clayton Act and West Virginia Code § 5A-3C-12 [Doc. 96 at 2-3]. However, Wasanyi's Motion is simply without merit, as the statutes he cites are completely inapplicable to this action. In general, the Clayton Act, 15 U.S.C.A. § 12 et seq., prohibits price discrimination, tying and exclusive dealing contracts, improper corporate mergers (e.g. acquisition of competing companies by one, and interlocking directorates. These practices are deemed

illegal when they might substantially lessen competition or tend to create a monopoly in any line of commerce. See *United States v. E.I. du Pont de Nemours & Co.*, 353 U.S. 586, 589 (1957). While Wasanyi argues that Dr. Catizone's pro bono services in this matter somehow constitute a violation of the Clayton Act, the same simply does not apply to Dr. Catizone's services in this case, regardless of whether he charges a fee. Additionally, Wasanyi also refers to a West Virginia statute, § 5A-3C-12.⁴ However, § 5A-3C-12 was repealed in 2009, and cannot possibly be applied to this matter. Accordingly, Wasanyi's Motion to Strike is denied, as is his Motion for Hearing on the Motion to Strike, given that the motion itself does not have merit.

In his Motion for Extension of Time to File Voir Dire, Jury Instructions, and Verdict Form [Doc. 111], Wasanyi avers that he is in custody in the Martinsburg Correctional Facility, and that, "his freedom to do this preparations [sic] is limited," and that his "handwritten forms . . . might not be legible." As such, Wasanyi requests additional time to file those documents. For good cause shown, this Court finds that defendant Wasanyi's Motion for Extension is hereby granted as to the issue of damages.

IV. Conclusion

For the reasons stated more fully above, defendant Wasanyi's **Motion to Dismiss [Doc. 58]**, **Motion to Strike [Doc. 96]**, and **Motion for Hearing on the Motion to Strike [Doc. 108]** are **DENIED**. The Government's Motion for Summary Judgment is **GRANTED** as to defendant David M. Wasanyi, and **DENIED AS MOOT** as to defendants Roger Lewis,

⁴ While defendant Wasanyi refers to West Virginia Code "50 A-3C-12" in the caption of his Motion, he refers solely to § 5A-3C-12 throughout the body of his Motion. However, the West Virginia Code does not have a § 50A-3C-12.

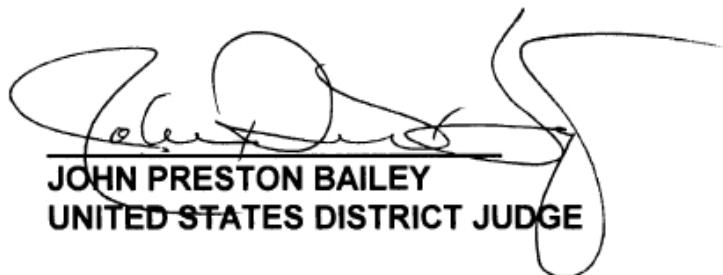
Amy Louise, CP, and CPCT, as those parties have entered into a settlement agreement with the Government.

However, defendant Wasanyi's **Motion for Extension of Time to File Voir Dire, Jury Instructions, and Verdict Form [Doc. 111]** is **GRANTED**, and the **Scheduling Order [Doc. 36]** is hereby **ORDERED AMENDED**, such as that the parties shall have until **May 26, 2017**, to file **Motions in Limine**, while **Objections** to the Motions in Limine shall be due by **June 9, 2017**. This Court notes that defendant Wasanyi need not submit a proposed Voir Dire, Jury Instructions, and Verdict Form, however, as this matter is set for a Bench Trial on the issue of damages. Additionally, the parties shall file a **Joint Pretrial Order** by **June 16, 2017**. This Court also **ORDERS** that, **insofar as it is practicable**, defendant Wasanyi file his prospective **Motions in Limine and Objections in legible format**. Finally, the **Final Pretrial Conference** and **Trial** in this matter are hereby **ORDERED CONTINUED GENERALLY** to a date and time to be set by this Court at a later date.

It is so **ORDERED**.

The Clerk is directed to transmit copies of this Order to all counsel of record herein and to the *pro se* defendant.

DATED: April 19, 2017.



JOHN PRESTON BAILEY
UNITED STATES DISTRICT JUDGE